[redacted]

JS 9/1/21
RJA 01/03/22

Number/Name: P-18-0020/Butanedioic acid, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 2,5-furandione and 1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester

[redacted]

SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance by **comparing it to structurally analogous chemical substances for which there is information on human health hazard.**

Based on the hazard determination and available **quantitative and/or qualitative** risk information, EPA **did not identify risks of concern for the PMN substance.**

Human Health Hazard:

- Absorption of the low molecular weight fraction (35% < 500, 57% < 1000) is poor all routes based on analogues.
- No identified health concerns

Exposure and Risk Summary

Workers

Risks were not identified for workers for sterotypic behavior, respiratory difficulty, impaired gait, loss of coordination hazard endpoints via inhalation exposure route based on quantitative hazard data for a monomer of the PMN, Dicyclopentadiene (DCP) CAS # 77-73-6 and a component of the new chemical (MOE = 617; benchmark MOE = 100).

Risks were identified for workers for reproductive and developmental toxicity hazard endpoints via dermal exposure route based on quantitative hazard data for a monomer of the PMN, Dicyclopentadiene (DCP) CAS # 77-73-6 and a component of the new chemical (MOE = 16.5; benchmark MOE = 100). Risks may be mitigated by the use of PPEs such as impervious gloves.

General Population

Risks were not identified for general population for reproductive and developmental toxicity hazard endpoints via drinking water (MOEAdult = 2,198; MOEInfant = 523; benchmark MOE =

100)and fish ingestion (MOE = 5,080; benchmark MOE = 100) based on quantitative hazard data for an analogue, Dicyclopentadiene (DCP) CAS # 77-73-6 and a component of the new chemical.

Consumers

Risks to consumers were not assessed because consumer use was not identified as a condition of use.

Potentially Useful Information:

- No testing required.

PART A

SAT Date: 10/24/217

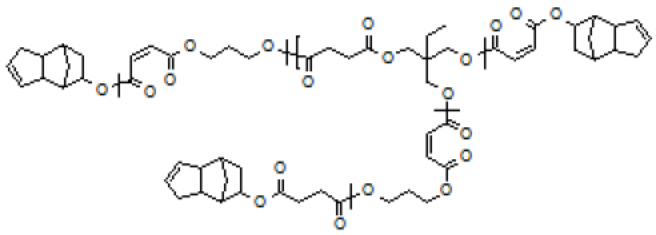
SAT Chair: Doritza Pagan-Rodriguez

Health Assessor: Keith Salazar

QC Reviewer: Louis Scarano, 10-31-17

Structure:

PMN: P-18-0020	Submitter: Myriant Corporation					Manu.	Import
Max. PV (KG):	500000	Binding Option Marked:				X	
MW: 535	35	% < 500	57	% <1000	CASNO.: None		

PMN Structure	Prop.	Meas.	Est.
	MP		
	BP		>500
	Pres.		at 760 mm Hg
	VP		<0.000001
	S-H2O		0.000019
	log P		6.72

Chemical Name: Butanedioic acid, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 2,5-furandione and 1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester

Analogs:

[redacted]

[redacted]

- **CASRN:**
- **Chemical Category:**
- **Chemical Category Health Concerns:**
  - none
- **Category Testing Strategy:**
  - Exposure based analysis
- **PMN Health Rating: 1**

- **SAT Key Words:**
  - NONE
- **Absorption:**
  Absorption of the low molecular weight fraction (35% < 500, 57% < 1000) is poor all routes based on analogs.
- **SAT Health Summary:**
  No identified health concerns
- **PMN Data:** (study summary, POD)
  - None
- **Analog Data:** (analog, structure, study summary, POD)

PMN or CAS No.	Chem. Name	Structure	TSCA Y/N
[redacted]			Y
			Y
			Y

- **Other Information:** (structural alert or component of interest, basis, etc.)
  - SDS
    - **SDS does not describe any hazard concerns**
- **Point of Departure Selected and Basis:**
  - Although no significant health concerns were identified, there are no hazard data to confirm the expected low toxicity.

[redacted]

Exposure Routes of Interest:

Route of Interest	
x	Inhalation:

x	Dermal:
x	Ingestion:

POD for Developmental and Reproductive Toxicity (57% of PMN)

- **POD type (NOAEL/LOAEL)** - NOAEL
- **POD Chemical:** - Dicyclopentadiene (DCP)
- **POD Route:** - Oral/Gavage
- **POD Endpoint:** - Reproductive and developmental toxicity
- **POD Value:** - 30mg/kg/day
- **POD Basis:** Based on several developmental and reproductive studies conducted and from the information accumulated by NTP for the DCP, all having a LOAEL of 100 mg/kg/day
- **POD Benchmark MOE:** 100
- **Reference:** - NTP's Toxicity Effects of Dicyclopentadiene (DCP) Cas # 77-73-6

POD for Neurotoxic Effects of the Dicyclopentadiene (DCP) (57% of PMN)

- **POD type (NOAEL/LOAEL)** - NOAEC
- **POD Chemical:** - Dicyclopentadiene (DCP)
- **POD Route:** - Inhalation
- **POD Endpoint:** - Sterotypic behavior, respiratory difficulty, impaired gait, loss of coordination
- **POD Value:** - 46 PPM (248.75 mg/m^3)
- **POD Basis:** two different sub chronic exposure studies on mice and rats
- **POD Benchmark MOE:** 100
- **Reference:** - NTP's Toxicity Effects of Dicyclopentadiene (DCP) Cas # 77-73-6

PART B

Focus Date:11-27-2017
Focus Assessor: Sailesh Surapureddi
QC: J Congleton and C. Baier-Anderson

USES and EXPOSURES:

- **Uses:** [redacted]

- **Worker Exposure:**
  - **Inhalation:** Exposure to Particulate (non volatile)
    Potential Dose Rate: [redacted] mg/day over [redacted] days/yr
  - **Dermal:** Potential Dose Rate: [redacted] mg/day over [redacted] days/yr

- **General Population Exposure:**
  - **Drinking Water:** ADR as high as **1.71E-02 mg/kg/day**
  - **Fish:** ADR as high as **7.40E-03 mg/kg/day**
  - **Air/Inhalation:** below modeling thresholds

- **Consumer Exposure:** Not expected

RISK CALCULATIONS:

- **Worker Calculations:**
  - There are no significant health concerns identified, there is no hazard data to confirm the expected low toxicity. So risks could not be quantified from the inhalation and dermal exposures to workers.

[redacted]

Worker Margin of Exposure (MOE) Calculations using Animal Inhalation POD and Engineering Report PDR

	Animal or Human POD			Worker Exposure				Human Breathing Rates						Benchmark MOE	Endpoint Type
Exposure Route	POD Conc. mg/m^3	POD Period hrs/day	POD Duration days/wk	Exposure mg/day Potential Dose Rate (PDR)	Total Worker Breathing Volume for PDR Exposure Period m^3	Worker Exposure Duration Hours/Day	Exposure Duration Days/Wk	Default	Worker	Structural Alert as % of PMN	POD Conc - Duration & Breathing Rate Correction $Scenario_{HEC}$ mg/m^3	Exposure TWA mg/m^3	**Margin of Exposure MOE**	100	NOAEL
Inhalation	2.5E+02	6.00	5	2.6E+00	10.0	8.00	5	4.90	10.00	57%	9.1E+01	2.6E-01	**616.84**	Fold Factor =	0.2

Risks were not identified for workers for sterotypic behavior, respiratory difficulty, impaired gait, loss of coordination hazard endpoints via inhalation exposure route based on quantitative hazard data for an analogue, Dicyclopentadiene (DCP) CAS # 77-73-6 and a component of the new chemical (MOE = 617; benchmark MOE = 100).

Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR

	Animal or Human			Human							Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/day Potential Dose Rate (PDR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Body Weight kg	Exposure mg/kg-day	Structural Alert as % of PMN	Margin of Exposure MOE	100	NOAEL
Dermal	3.0E+01	5	100%	1.7E+03	5	15%	80	2.1E+01	57%	**16.5**	[redacted]	

Risks were identified for workers for reproductive and developmental toxicity hazard endpoints via dermal exposure route based on quantitative hazard data for an analogue, Dicyclopentadiene (DCP) CAS # 77-73-6 and a component of the new chemical (MOE = 16.5; benchmark MOE = 100).

- **General Population Calculations:**
  - There are no significant health concerns identified, there is no hazard data to confirm the expected low toxicity. So risks could not be quantified from the inhalation and oral exposures to general population.

[redacted]

Population/Consumer Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR											
	Animal or Human			Human						Benchmark MOE	Endpoint Type
Exposure Route	POD mg/kg-day	POD Exposure Duration Days/Wk	POD Route % Absorp	Exposure mg/kg-day Acute Dose Rate (ADR)	Exposure Duration Days/Wk	Exposure Route % Absorp	Multiplier for Susceptible Subpopulations	Structural Alert as % of PMN	Margin of Exposure MOE	100	NOAEL
Drinking Water (adult)	3.0E+01	5	100%	1.7E-02	7	100%	10	57%	**2,198.48**	[redacted]	
Drinking Water (infant	3.0E+01	5	100%	1.7E-02	7	100%	42	57%	**523.45**		
Fish Ingestion	3.0E+01	5	100%	7.4E-03	7	100%	10	57%	**5,080.27**		

Risks were not identified for general population for reproductive and developmental toxicity hazard endpoints via drinking water (MOEAdult = 2,198; MOEInfant = 523; benchmark MOE = 100)and fish ingestion (MOE = 5,080; benchmark MOE = 100) based on quantitative hazard data for an analogue, Dicyclopentadiene (DCP) CAS # 77-73-6 and a component of the new chemical.

- **Consumer Calculations:** Risks to consumers were not assessed because consumer use was not identified as an intended use.